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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,111	05/17/1999	TAKA-AKI SATO	48962-A-PCT-	4836

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JOHN P WHITE
COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/230,111	Applicant(s) SATO ET AL.	
	Examiner Anne Holleran	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *121-141* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *121-141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *23,24* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The amendment filed May 7, 2002 is acknowledged. Claims 27-76 were canceled. Claims 121- 141 were added.

Claims 121-141 are pending and examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

3. The objection to claims 27, 50, 52 and 75 for not complying with the requirements of 37 CFR 1.821-1.825 is withdrawn in view of the amendment.

4. The rejection of claims 27-37, 40-46, 50-62, 65-70, 75 and 76 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendment canceling the claims.

5. The rejection of claims 27-37, 43-46, 50, 51, 52-62, 68-70, 75 and 76 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment canceling the claims. However, this ground of rejection is applied to new claims 121-141. See below.

6. The rejection of claims 27-37, 40-42, 50-62, 65-67, 75, and 76 under 35 U.S.C. 102(e) as being anticipated by Reed et al (U.S. Patent 5,876,939; issued March 2, 1999; effective U.S.

filing date March 27, 1995) is withdrawn in view of the cancellation of the claims. However, this ground of rejection is applied to new claims 121-132 and 139-141. See below.

New Grounds of Rejection:

7. Claims 121-141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 121 and 139 recite the phrase "consisting essentially of" for the purpose of describing the amino acid sequence of a peptide. Absent a definition in the specification that clearly sets forth the scope of this phrase, such a recitation is indefinite. The phrase "consisting essentially of" is used in situations where it is clear that addition of other elements may not significantly alter a claimed composition. In the case of peptides, it is not clear how a peptide may have additional amino acids added that would not significantly alter the structure of the peptide. For the purposes of examination, the phrase "consisting essentially of" is interpreted as "comprising".

8. Claims 121-141 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for screening for compounds that disrupt the binding of Fas with FAP, does not reasonably provide enablement for methods for screening for compounds that disrupt the binding of a CD4 receptor, a p75 receptor, a serotonin receptor, a serotonin 2B receptor, a NMDA receptor, or a K^+ channel, or a signal transducing protein that is a peptide consisting essentially of 3-13 amino acids having at its carboxyl terminus the amino

acid sequence (S/T)-X-(V/I/L) (SEQ ID NO: 4) with a cytoplasmic protein containing the sequence (G/S/A/E)-L-G-(F/I/L) (SEQ ID NO: 1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See Ex parte Forman, 230 USPQ 546, BPAI, 1986.

The specification confines its exemplified teachings to how to screen for compounds that disrupt the binding of Fas with FAP. The prior art also teaches such methods, and also teaches that the use of such screening methods is to discover agents that may be used to modulate apoptosis. The basis for this teaching is that the prior art demonstrates that the association between Fas and FAP is a step that is required in signaling of apoptosis (see Reed et al, U.S. Patent 5,876,939, col. 29, line 10 – col. 30, line 47). The instant specification fails to teach how to use screening methods for all of the possible combinations of cytoplasmic protein and signal-transducing protein because the specification fails to teach the biological significance of any other combination, other than that of Fas with FAP. Thus, the specification appears to provide an invitation to research to discover uses of the most of the claimed screening assays. Therefore, it would require undue experimentation to first establish the biological significance of the

association between a cytoplasmic protein and a signal-transducing protein, and then to use this information to know how to use the full scope of the claimed methods.

The amendment to the claims, and applicants' arguments are insufficient to overcome this ground of rejection. Applicants assert that the specification teaches methods of screening with respect to the association of p75 with FAP. This is not persuasive, because although the specification teaches that there appears to be an association between p75 and FAP, the specification fails to teach the biological role of the interaction between the two proteins. Therefore, one of skill in the art would not be able to use the claimed methods of screening for anything other than as a research tool to discover the biological significance of the association between p75 and FAP.

With respect to the claims where the claimed methods are directed to screening methods for identifying compounds that inhibit the specific binding between a CD4 receptor, a serotonin receptor, a serotonin 2B receptor, a NMDA receptor, or a K^+ channel and a cytoplasmic protein containing the sequence (G/S/A/E)-L-G-(F/I/L) (SEQ ID NO: 1), the specification fails to provide adequate support for the claimed methods. The specification fails to teach the identity of the cytoplasmic proteins that interact with these receptors. Thus, one of skill in the art would first have to discover the identity of these cytoplasmic proteins and then make methods for detecting these cytoplasmic proteins. Secondly, because the specification fails to teach the biological role of the interaction between these receptors and the unidentified cytoplasmic proteins, one of skill in the art would not know how to use the claimed methods for anything other than further research of these receptors.

With respect to the claims where the claimed methods are directed to screening methods for identifying compounds that inhibit the specific binding between a signal transducing protein that is a peptide consisting essentially of 3-13 amino acids having at its carboxyl terminus the amino acid sequence (S/T)-X-(V/I/L) (SEQ ID NO: 4) and a cytoplasmic protein containing the sequence (G/S/A/E)-L-G-(F/I/L) (SEQ ID NO: 1), the scope of the claims is so broad as to include yet to be discovered signal transducing proteins. Therefore, one of skill in the art would first have to discover the identity of the signal transducing protein, and methods for its detection, and then one of skill in the art would have to discover the identity of the cytoplasmic protein. Secondly, one of skill in the art would be required to discover the biological significance to the interaction between these signal transducing proteins and cytoplasmic proteins. Without knowing the biological significance of the interaction between the two proteins, one of skill would be in the position of practicing a method that identified compounds that would not have practical use until further research provided a reason for inhibition of an interaction between a signal transducing protein and a cytoplasmic protein.

Given the breadth of the claims with respect to the scope of the disclosure of the specification and what is known in the prior art, one of skill in the art would be forced to engage in undue further experimentation in order to know how to use the claimed screening methods and in order to know how to use the products that would be identified from the claimed screening methods.

9. Claims 121-132, and 139-141 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the amendment introduces new matter into the specification.

Claims 121 and 139 contain the recitation "consisting essentially of 3-13 amino acids having at its carboxyl terminus the amino acid sequence (S/T)-X-(V/I/L) (SEQ ID NO: 4)" as limitation for the structure of a signal transducing protein. The specification as originally filed does not appear to support such a limitation. Furthermore, the passages pointed to by applicants fails to provide support so that one could readily envision the genus of compounds. Furthermore, the specification fails to provide support for the phrase "consisting essentially of". Therefore, claims 121-132 and 139-141 introduce new matter into the specification.

10. Claims 121-132 and 139-141are rejected under 35 U.S.C. 102(e) as being anticipated by Reed et al (U.S. Patent 5,876,939; issued March 2, 1999; effective U.S. filing date March 27, 1995).

Claims 121-132 and 139-141 are interpreted to encompass methods where the signal transducing protein is the Fas receptor, because the claims are drawn to methods of screening where the cytoplasmic protein consists essentially of 3-13 amino acids having at its carboxyl terminus the amino acid sequence (S/T)-X-(V/I/L) (SEQ ID NO: 4).

Reed discloses methods for screening for compounds that disrupt the binding of Fas (a signal transducing protein that is a receptor) with FAP (a cytoplasmic protein) (see column 13, line 51- column 14, line 6; and column 14, lines 18-20). The screening assay may be performed by a yeast two-hybrid assay or by assay of the level of a reporter gene (column 15, lines 13-27).

The assay may be adapted for use in mammalian cells (column 15, lines 42-47). The compounds that may be screened are peptides, peptidomimetics, inorganic compounds, organic compounds (see column 13, lines 62-65). Reed discloses that Fas is expressed in breast, colon, and prostate cells (see column 1, lines 44-47). It is well known in the art that Fas is expressed in T-cells. Thus, Reed discloses methods of screening that are the same as that claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Anne L. Holleran
Patent Examiner
August 11, 2002

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER